



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1388]

Responsible Innovation in Dietary Supplements; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled “Responsible Innovation in Dietary Supplements.” The purpose of the public meeting is to give interested parties an opportunity to present ideas for facilitating responsible innovation in the dietary supplement industry while preserving and strengthening FDA’s ability to efficiently and effectively protect the public from unsafe and unlawful products.

DATES: The public meeting will be held on May 16, 2019, from 8:30 a.m. to 4 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by July 15, 2019. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at Food and Drug Administration, Center for Food Safety and Applied Nutrition, Wiley Auditorium, 5001 Campus Dr., College Park, MD 20740.

FDA is establishing a docket for public comment on this meeting. You may submit comments as follows: Submit comments online at <https://www.fda.gov/oc/submit-comment>. Comments received by comments until 11:59 p.m. Eastern Time at the end of July 15, 2019. Comments received by

mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2019-N-1388 for "Responsible Innovation in Dietary Supplements; Public Meeting; Request for Comments." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about

FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Juanita Yates, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-009), 5001 Campus Dr., College Park, MD 20740, 240-402-1731, email: [Juanita.yates@fda.hhs.gov](mailto:Juanita.yates@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

On February 11, 2019, FDA announced new efforts to strengthen the regulation of dietary supplements by modernizing and reforming FDA's oversight (see Statement from FDA Commissioner Scott Gottlieb, M.D., on the Agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight, available at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm631065.htm>). FDA's announcement acknowledged the need to ensure that our regulatory framework is flexible enough to adequately evaluate product safety without unnecessarily restricting innovation. We invite public input about whether and how we should adjust our current dietary supplement regulatory approach to better allow for innovation and growth in the dietary supplement

marketplace while maintaining and strengthening our ability to efficiently and effectively evaluate product safety and protect the public health.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) (Pub. L. 103-417) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) and defined “dietary supplement,” in part, as a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:

- (A) a vitamin;
- (B) a mineral;
- (C) an herb or other botanical;
- (D) an amino acid;
- (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E).

Section 201(ff)(1) of the FD&C Act (21 U.S.C. 321(ff)(1)).

DSHEA clarified that dietary supplements are generally subject to regulation as foods under the FD&C Act but also included dietary supplement-specific adulteration and misbranding provisions. Among other things, DSHEA provided authority for FDA to establish current good manufacturing practice requirements for dietary supplements and clarified the statements of nutritional support that can be made in product labeling. Dietary supplement manufacturers and distributors are responsible for selling products that comply with these requirements. FDA is responsible for regulating dietary supplements and has authority to take enforcement action when dietary supplements are adulterated or misbranded.

DSHEA also added section 413 of the FD&C Act (21 U.S.C. 350b), which defines the term “new dietary ingredient” (NDI) and describes requirements for NDIs. Among other things, section 413 of the FD&C Act requires the manufacturer or distributor of an NDI, or of a dietary supplement containing an NDI, to submit a premarket notification to FDA at least 75 days before introducing the NDI or dietary supplement into interstate commerce, unless the NDI and any other dietary ingredients in the dietary supplement have been present in the food supply as an article used for food in a form in which the food has not been chemically altered (21 U.S.C. 350b(a)(1)).

DSHEA contemplated a dynamic dietary supplement market with a role for innovation. In the 25 years since DSHEA was enacted, the dietary supplement market has grown significantly. What was once a \$4 billion industry comprising about 4,000 products is now an industry worth more than \$40 billion with more than 50,000--and possibly as many as 80,000 or even more--products available to consumers. Innovative new products involving novel technologies related to ingredients, manufacturing processes, and delivery systems represent a substantial portion of this growth.

A robust NDI notification process is an integral part of the DSHEA framework and represents FDA’s only opportunity to evaluate the safety of NDIs in dietary supplements before they become available to consumers. Despite the expanded marketplace, however, we have only received about 1,200 NDI notifications since DSHEA’s enactment. FDA recognizes that not every new dietary supplement product is subject to the notification requirement, so we continue to provide clarifications on when premarket notifications are required.<sup>1</sup> A transparent, common

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<sup>1</sup> See, e.g., Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues (August 2016), available at <https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm257563.htm>. This draft guidance, when finalized, will represent FDA’s current thinking on this topic.

understanding of the requirements surrounding dietary ingredient status and notification, with predictable expectations regarding compliance and consequences for non-compliance, will help our regulatory processes operate effectively. Public discussion of these issues will further our efforts to strengthen regulation of dietary supplements through modernization and reform and help us better protect the public health.

## II. Topics for Discussion at the Public Meeting

FDA will host a one-day public meeting to provide interested parties an opportunity to discuss various issues related to responsible innovation in dietary supplements, including the following topics:

- (1) The scope of the phrase “dietary substance for use by man to supplement the diet by increasing the total dietary intake,” as used in DSHEA (section 201(ff)(1)(E) of the FD&C Act);
- (2) Understanding exceptions to the requirement for premarket notification, and evaluating whether and how growth in the marketplace since 1994 has altered the impact of those provisions;
- (3) Potential commercial or marketing advantages to incentivize responsible innovation; and
- (4) Promoting overall compliance with the premarket notification requirement through enforcement.

The issues discussed at the public meeting, including the above topics, and any comments submitted to the docket by July 15, 2019, will help us evaluate how to proceed with our efforts to modernize and reform FDA’s oversight of dietary supplements.

## III. Participating in the Public Meeting

*Registration:* To register for the public meeting, please visit the following website:  
<https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm632939.htm>.

Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in attending this public meeting should register by May 6, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting. Please visit the website at <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm632939.htm> for this information as well as the final meeting agenda.

If you need special accommodations due to a disability, please contact Juanita Yates (see FOR FURTHER INFORMATION CONTACT) no later than May 1, 2019.

*Requests for Oral Comments:* During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We are seeking a broad representation of ideas and issues presented at the meeting. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their remarks and to request time for a joint comment. After registration closes, we will determine the amount of time allotted to each participant and the approximate time each oral comment is to begin and will select and notify participants by May 10, 2019. All requests to make oral comments must be received by the close



of registration on May 1, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Those without internet or email access can register and/or request to participate by contacting Juanita Yates by the above dates (see FOR FURTHER INFORMATION CONTACT).

*Streaming Webcast of the public meeting:* This public meeting will also be webcast. Please visit the following website to register:

<https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm632939.htm>.

FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

*Transcripts:* Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It also may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at

<https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm632939.htm>.

Dated: April 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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